U.S. Department of Justice

United States Attorney
Southern District of New York

86 Chambers Street
New York, New York 10007

MEMO ENDORSED

July 11, 2019

VIA ECF

The Honorable Valerie E. Caproni
Thurgood Marshall
United States Courthouse
40 Foley Square
New York, NY 10007

USDC SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #:
DATE FILED: 7/11/2019

Re: *The New York Times Company, et. al., v. United States Food and Drug Administration*, 19 Civ. 4740 (VEC)

Dear Judge Caproni:

This Office represents the United States Food and Drug Administration ("FDA") in the above-referenced action brought under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"). On behalf of the parties, we write pursuant to this Court's Order, Dkt. No. 8, and in advance of the initial pretrial conference scheduled for July 19, 2019, at 10:00 AM, *see id.* For the reasons stated herein, the parties respectfully request that the Court enter an order adopting the proposed schedule set forth below. Further, because this is an action brought under FOIA, the parties respectfully request to be relieved of the obligation to submit a proposed Civil Case Management Plan and Scheduling Order. *See* Local Civil Rule 16.1 ("Matters involving . . . reviews from administrative agencies are exempted from the mandatory scheduling order required by Fed. R. Civ. P. 16(b)."). The parties do not anticipate that discovery will be necessary to resolve Plaintiffs' claims for relief. As noted below, the parties also request that the Court adjourn the initial pretrial conference until after the completion of the schedule proposed below (i.e., for a date after November 15, 2019).

(1) ***A brief description of the case, including the factual and legal bases for the claim(s) and defense(s)***

Plaintiffs The New York Times Company and Sheila Kaplan (jointly, "The Times") have submitted two FOIA requests to FDA for documents related to Juul Labs, Inc. ("Juul"). Specifically, in June 2018, The Times sought "a copy of all materials that are submitted in any form, to the FDA, from [Juul] or its representatives, lawyers, lobbyists, and other parties, that are responsive" to a April 24, 2018, request sent by FDA to Juul for certain documents (the "June 2018 Request"). And in October 2018, The Times sought "marketing and advertising records, and sales strategy records, that the FDA obtained from Juul during its visit to headquarters the last week of September" (the "October 2018 Request"). Among other relief sought in this action, Plaintiffs seek an order compelling FDA to produce those records.

FDA has communicated with The Times regarding both requests. As of today's date, FDA has not produced any documents responsive to either request. Specifically, with respect to the June 2018 Request, FDA informed The Times in November 2018 that, pursuant to 21 C.F.R.

§ 20.61(e)(1), FDA was providing predisclosure notification to Juul, as well as the opportunity to object to disclosure of any part of the records and state all bases for its objections. FDA informed Plaintiffs that it instructed Juul "to follow a response schedule that extends through April [2019]." Juul has now completed that review, and FDA is currently reviewing Juul's objections and processing the June 2018 Request. The parties jointly propose that FDA produce non-exempt responsive records in accordance with the schedule set forth below.

On November 28, 2018, FDA also informed The Times that it had denied the October 2018 Request in its entirety under FOIA Exemption (7)(A). The Times filed an administrative appeal of that denial on January 24, 2019. As of today's date, the Department of Health and Human Services has not rendered a decision with respect to that appeal. Although FDA's position is that the denial was appropriate, FDA has decided to reprocess Plaintiffs' October 2018 Request given changed circumstances and the particular facts of this case. As detailed below, the parties propose that FDA produce all non-exempt responsive records for this request by September 5, 2019. FDA anticipates providing Juul with the opportunity to object to disclosure of any part of the records prior to FDA's production on or before September 5, 2019. The Times' position is that FOIA Exemption 4 does not apply to these records. The Times has informed FDA that it objects to the pre-disclosure notification procedure in this case, but that it does not intend to seek relief from this Court regarding the issue.

(2) ***Basis for Subject Matter Jurisdiction***

Plaintiffs have alleged that this Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B). FDA does not assert a subject matter jurisdiction defense.

(3) ***Any Contemplated Motions***

In the event that the parties do not resolve Plaintiffs' claims without need for further intervention from the Court, the parties anticipate filing cross-motions for summary judgment.

(4) ***The Prospect for Settlement***

Although the parties believe that settlement discussions at this time are premature, the parties have agreed to meet and confer regarding potential settlement subsequent to FDA's productions.

(5) ***Proposed Schedule***

The parties have agreed upon a proposed schedule for this action. The parties thus respectfully request that the Court adopt the proposed schedule set forth below.[1]

- On or before July 31, 2019, FDA will release any and all non-exempt records and non-exempt portions of records for 715 Adobe PDF files identified by FDA as responsive to the June 2018 Request.

- On or before September 2, 2019, FDA will release any and all non-exempt records and non-exempt portions of records for an additional 2,947 Adobe PDF files identified by FDA as responsive to the June 2018 Request.

- On or before September 5, 2019, FDA will release any and all non-exempt records and non-exempt portions of records identified by FDA as responsive to the October 2018 Request.

- On or before September 16, 2019, FDA will release any and all non-exempt records and non-exempt portions of records for an additional 680 Adobe PDF files identified by FDA as responsive to the June 2018 Request.

- On or before October 1, 2019, FDA will release any and all non-exempt records and non-exempt portions of records for 353 Microsoft Excel files identified by FDA as responsive to the June 2018 Request.

- On or before October 16, 2019, FDA will release any and all non-exempt records and non-exempt portions of records for 9 MP3 files identified by FDA as responsive to the June 2018 Request.

- On or before October 31, 2019, FDA will release any and all non-exempt records and non-exempt portions of records for 51 MP4 files identified by FDA as responsive to the June 2018 Request.

- After each production, the parties will meet and confer to discuss that production, including whether The Times intends to contest the adequacy of FDA's search, and the scope of the relevant production or FDA's claimed withholdings, if any.

- On or before November 15, 2019, the parties will provide the Court with a joint status report including, if necessary, a proposed briefing schedule for any matters to be resolved via motions for summary judgment.

[1] FDA's position is that, because of the unique nature of FDA's pre-notification requirements and the significant progress already made in processing the June 2018 and October 2018 Requests, this proposed schedule should not be relied upon by plaintiffs in other actions as it pertains to production or processing timetables in FOIA cases. The Times notes FDA's concerns but makes no commitment to not cite these timetables in other cases.

Because the parties have agreed on the above proposed schedule, they respectfully request that the Court adjourn the initial pretrial conference currently scheduled for July 19, 2019, until after they submit their joint status report on November 15, 2019. This is the parties' first request for an adjournment. Pursuant to Your Honor's Individual Practice 3.A, the parties are available for such an initial pretrial conference on the following Friday mornings: November 22, 2019, December 6, 2019, and December 13, 2019.

Thank you for your consideration of this matter.

Respectfully,

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cc: Counsel of record (via ECF)

Application GRANTED. The parties' proposed productions schedule is ADOPTED. The IPTC is ADJOURNED to **November 22, 2019, at 10:00 a.m.** In their **November 15, 2019** status update, in addition to proposing a schedule for briefing any motions for summary judgment, the parties must inform the Court whether, in their view, the IPTC would be beneficial or should be cancelled.

SO ORDERED.

7/11/2019

HON. VALERIE CAPRONI
UNITED STATES DISTRICT JUDGE